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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,546	01/18/2002	Gregory A. Demopulos	OMER118473	6615

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EXAMINER	
YOUNG, MICAH PAUL	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,546	DEMOPULOS ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38,39,44-54,59,60,73-76 and 81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38,39,44-54,59,60,73-76 and 81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/17/06,1/9&30/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Response dated 1/9/06, Information Disclosures Statement dated 1/30/06 and 2/17/06.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38,39,44-54,59,60,73-76 and 81 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific catabolic inhibiting agents such as MAP Kinase inhibitors and specific anabolic compounds such as interleukin, does not reasonably provide enablement for all possible compounds defined by their function of inhibiting catabolism or anabolic compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use or envision the invention commensurate in scope with these claims. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;
The claims are drawn to a method of inhibiting cartilage degradation comprising the administration of all compounds that can classify as anabolic chondroprotective agents and all compounds that can and do classify as catabolic inhibiting chondroprotective agents.
(B) The nature of the invention;
The nature of the invention is that of a method of preventing damage to cartilage using well compounds well know for these properties.
(C) The state of the prior art;
The prior art, acknowledges the cartilage repairing properties of the specific compounds recited in the dependent claims. Hunziker (USPN 5,206,023) establishes at the time of the

invention chemotactic agents, defined separately by applicant, are useful in treating and repairing defects or lesions in cartilage. These compounds include inhibitors of catabolic activity such as TNF-alpha and anabolic compounds such as TGF-betas (col. 7, lin. 62-col. 8, lin. 7).

(D) The level of one of ordinary skill;

One of ordinary skill would be able to combine compounds of known properties in order to combine and improve their result. However in order to meet the limits of the claims, an artisan would have to test and verify each and every compound to asses their anabolic and catabolic inhibiting properties.

(E) The level of predictability in the art;

Given the wide range of possible compounds, the level of predictability is low. Compounds would need to essayed and all properties determined before a combination can be made of the described compounds. This would cause undue experimentation for every known compound.

(F) The amount of direction provided by the inventor;

The inventor des not provide much direction since the specific compounds are known for treating cartilage damage.

(G) The existence of working examples;

The specification does not appear to contain any working examples of composition combing the compounds as defined and being used in the manner recited in the claims. There do not appear to be any working examples of a cartilage repairing or treating composition created by the examples.

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

As discussed above, one of ordinary skill in the art would have to test every known compound to determine the anabolic properties and catabolic inhibiting properties of said compound.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 53 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites that fragments, deletions, additions, amino acid substitutes, mutations and modifications would be useful for the invention. However it would be impossible to determine the meets and bounds of the claim. How can additions, deletions, fragments and other

parts or smaller subsets of a compound retain any of the original property? Further how can a claim so broad be properly searched? Applicant must clarify this claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 38,39,44-54,59,60,73-76 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al (USPN 6,096,728 hereafter '728) and Hunziker (USPN 5,206,023 hereafter '023). The claims are drawn to method of inhibiting cartilage degradation in a joint comprising delivering to the joint a composition comprising two chondroprotective agents.

2. The '728 patent teaches a method and formulation for the treatment of inflammatory diseases (abstract). The method requires the administration of a formulation comprising Interleukin 1 inhibitors in combination with various therapeutic compounds and carriers (col. 25, lin. 52-65). The additional compounds include MAP kinase inhibitors such as SB203580 (col. 32, lin. 17), and anti-inflammatory agents when the composition is used for the treatment of chronic osteoarthritis, psoriatic arthritis and/or rheumatoid arthritis (col. 34, lin. 6-24). The compounds can be injected intra-articulately (col. 35, lin. 13-col. 36, lin. 60) before, during or

after a trauma or surgical procedure (*Ibid.*). The reference is however silent to the inclusion of fibroblast growth factors.

3. The '023 patent teaches methods for the treatment and repair of defects of lesions in cartilage (abstract). The method includes the delivery via injection a composition comprising various therapeutic compounds such as fibroblast growth factors (col. 4, lin. 49-64). The growth factors are combined with other components in methods to treat defects in knee cartilage (examples).

4. Since both '728 and '023 disclose compositions for the treatment of cartilage damage, it would be well within the level of skill in the art to combine them in order to provide an improved cartilage treatment composition. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. *See* In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)

5. With these things in mind it would have been obvious to combine the compounds of '023 and '728 in order to produce an improved method of treatment. The method of '728 requires a mixture of ingredients including anti-inflammatory agents, and inhibitors of catabolic action. It would be within the level of skill in the art to combine these compounds with those of '023 since the compounds of both references are useful in the treatment of damaged cartilage. It would have been obvious to make this combination with an expected result of an improved treatment method for damaged cartilage.

Response to Arguments

6. Applicant's arguments filed 2/6/06 have been fully considered but they are not persuasive. Applicant argues that these exists no motivation to combine the references to arrive at the invention.

7. It is the position of the Examiner that the motivation to combine the reference is found in Hunziker. The reference discloses compounds useful in the treatment and repair of lesions and defects in cartilage. The compounds recited include tumor necrosis factors (TNF alphas) described by applicant as inhibitors of cartilage catabolism and TGF-betas, described by applicant as anabolic agents. This disclosure provides sufficient motivation to combine both anabolic and catabolic inhibiting compounds in order to repair and treat cartilage damage. The claims are drawn to the inhibition of cartilage damage, which the prior art discloses. The Hunziker reference, though not teaching all of the specific compounds, does in fact discloses that anabolic and catabolic inhibiting compounds can be used to treat cartilage damage. Collins provides the specific MAP kinase inhibitor, and other compounds such as anti-inflammatory agents. The Hunziker provide the motivation to combine compounds that help treat cartilage damage, even though they might be classified differently. Applicant is invited to provide any experimental data that would provide a patentable distinction between the proposed method and that of the prior art. The prior art provides a method of treating cartilage in the joint of a patient. Until such time where a distinction can be made between the methods the claims will remain obviated.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1618

MP Young

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER